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June 28, 2013

Via ECF

The Honorable Douglas E. Arpert
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, N.J. 08608

Re: *AstraZeneca/Pozen v. DRL, Lupin & Anchen*
Civil Action No. 3:11-CV-2317-JAP-DEA

Dear Judge Arpert:

As per Your Honor's instructions during the June 21, 2013 scheduling conference, DRL writes in response to Pozen's letter dated June 26th (D.E. 148) to explain why additional claim construction is unwarranted.

Pozen concedes that the Court already construed the NSAID coating term,¹ and that this term contains the phrase that Pozen now wants re-construed. Pozen fails to mention that the Court adopted the construction of the NSAID coating term that Pozen proffered and agreed with Pozen that this claim term had a "plain and ordinary meaning" and that the "language of the claim itself is clear."² Nevertheless, Pozen argues that the Court's construction of part of this term should be redone for three reasons. None of these reasons is persuasive.

First, Pozen argues that the NSAID coating term includes more than the part it now wants construed and no one paid attention to that part when the Court construed the full term. Pozen dismisses the prior claim construction as though the eleven (11) words "prevents the release of essentially any NSAID from said dosage form" were somehow AWOL when the Court construed it. Indeed, Pozen rechristens this term the "35-word phrase" as though the "high"

¹ "a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher."

² See D.E. 142, p. 10; D.E. 67, *Plaintiffs' Opening Markman Submission*, p. 6, ("AstraZeneca and Pozen submit that this phrase should be given its customary and ordinary meaning.").

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number of its words suggests a need for further clarification. But the Court held that the NSAID coating term had a “plain and ordinary meaning” and its words were already “clear.” A claim term cannot be clear, plain and ordinary if part of it is not. If the Court retains its prior “plain meaning” construction of the NSAID coating term, then the part of it that Pozen now wants to construe must already be “plain” and “clear.” If that part is, as it must be under the Court’s prior “plain meaning” construction, already clear, plain and ordinary, what exactly is left to be done? Indeed, if the Court were to construe part of the NSAID coating term after finding its entirety “plain” and “clear,” it would necessarily have to retract those findings to assign any other meaning to any part of it.

Second, Pozen says it needs reconsideration of the NSAID coating term construction because it now knows details regarding DRL’s proposed ANDA product that it did not know last year when the parties briefed and argued claim construction. Pozen wants to recast its claim construction around DRL’s accused product. But that is improper. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331 (Fed. Cir. 2006): “[C]laims may not be construed with reference to the accused device.” *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002); *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc). The Court is not supposed to construe the claims in order to capture or exclude DRL’s product. *Id.* Pozen’s new knowledge of the characteristics of DRL’s product is not a proper basis for a renewed claim construction. A patent should be construed based upon the intrinsic evidence. If it were proper to use an accused product’s attributes to bias the claim construction process, claim construction would be conducted at the end of the case when the product’s attributes would be well defined instead of – as our Local Patent Rules require – at the beginning. Accordingly, Pozen’s new knowledge about DRL’s product cannot be a basis for redoing claim construction.

Third, Pozen contends there is now a dispute about what some portion of the NSAID coating term means and that this dispute requires more claim construction. But whenever courts assign a “plain meaning” to a claim, that leaves open a potential dispute between the parties as to what that plain meaning is, and how that plain meaning applies to an accused product. Thus, in our view, the fact that there is a dispute over a plain meaning claim construction is not new and is hardly a basis to redo claim construction.³

Finally, Pozen argues that claim construction will not cause delay. Of course, that is not an argument for doing claim construction – it is an attempt to refute in advance an argument against claim construction. Nevertheless, if you allot four months for claim construction – as Pozen’s schedule does – it is obvious that there will be some delay. The whole purpose of this exercise according to Pozen is to get clarity on a claim term and Pozen will inevitably delay at

³ We also note that keeping this dispute alive gives neither party an unfair advantage. Both parties need to move ahead with discovery and address the infringement question in their expert reports – which is exactly what happens when any Court assigns a “plain meaning” construction.

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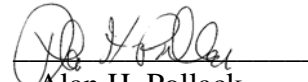
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least some discovery until it has that clarity. We think the delay is unnecessary and we should move the case forward.

The '907 patent has already had claim construction terms briefed twice. First by Pozen, DRL and Lupin, (D.E. 67, 69) and then subsequently and discretely by Pozen and Anchen (D.E. 100, 101). Pozen's suggested third pass on the same NSAID coating term, or a portion of it, in the same case by the same parties should not proceed because it is wasteful, will cause unnecessary delay and undermine the claim construction already done.

For all the reasons set forth here, DRL asks the Court to rest on the claim construction already done and its finding that the NSAID coating term has a "plain and ordinary" meaning.

Respectfully submitted,


Alan H. Pollack

cc: Counsel of Record (by e-mail)